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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ROBERT E. HANSON  
FULBRIGHT & JAWORSKI, LLP  
600 CONGRESS AVENUE  
SUITE 2400  
AUSTIN, TX 78701

EXAMINER

KUBELIK, ANNE R

ART UNIT PAPER NUMBER

1638

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

**Application No.**

09/818,921

**Applicant(s)**

LUNDQUIST ET AL.

**Examiner**

Anne R. Kubelik

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. The finality of the office Action mailed 17 June 2003 is withdrawn in light of the new rejections below:
2. Claims 10-32 are pending.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The rejection of claims 10-24, 26-27 and 29-32 under 35 U.S.C. 103(a) as being unpatentable over Tomes et al (US Patent 5,886,244, filed June 1988) in view of each of Barton et al (1987, Plant Physiol. 85:1103-1109), Vaeck et al (1987, Nature 328:33-37) and Adang et al (1985, EP 142,924) is withdrawn in light of the issuance of U.S. Patent No. 5,484,956.
5. The rejection of claim 25 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Tomes et al (US Patent 5,886,244, filed June 1988) in view of each of Barton et al (1987, Plant Physiol. 85:1103-1109), Vaeck et al (1987, Nature 328:33-37) and Adang et al (1985, EP 142,924), as applied to claims 10-24, 26-27 and 29-32 above, and further in view of Adang et al (US Patent 530,831, filed September 1988) is withdrawn in light of the issuance of U.S. Patent No. 5,484,956.
6. The rejection of claims 10-15, 18-24, 27, 29 and 31-32 remain rejected under 35 U.S.C. 103(a) as being unpatentable over each of Klein et al; (1989, Plant Physiol. 91:440-444), Klein et al (1988a, Proc. Natl. Acad. Sci USA 85:4305-4309), Klein et al (1988b, Bio/technol. 6:559-563) and Sanford et al (US Patent 5,036,006, filed June, 1986) in view of Shillito et al (US Patent 5,350,689, filed November, 1988) is withdrawn in light of the issuance of U.S. Patent No. 5,484,956.

***Claim Objections***

7. Claims 1-13 and 16-31 are objected to because a comma should be inserted before “wherein”.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 10-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of bombardment of embryogenic maize cells for the production of transformed maize plants, does not reasonably provide enablement for a method of bombardment of any other regenerable maize tissues for the production of transformed maize plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method for producing a fertile transgenic maize plant wherein any regenerable maize cells are bombarded with microprojectiles, followed by the regeneration of a fertile maize plant therefrom. Such regenerable maize cells could include roots, shoots, shoot tips, apical meristems, male or female floral parts, or leaves, as well as organogenic callus derived therefrom. In contrast, the specification only produces guidance for obtaining whole, fertile transgenic maize plants following the bombardment of regenerable

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embryogenic cells in the form of callus or suspension cultures that have been derived from immature embryos. No guidance is provided for the regeneration of any transformed plant, fertile or otherwise, from any other type of maize tissue.

Whole plant regeneration in maize is unpredictable and largely limited to somatic embryogenesis from embryogenic callus or suspensions. Green et al (1975, Crop Science 15 :417-421) teach the general recalcitrance of maize to whole plant regeneration, and the failure of explants such as shoots, flowers, and mature embryos to produce callus that can regenerate whole plants ( pg 417, column 1, penultimate paragraph). Green et al (1975) ultimately obtained success by using portions of immature maize embryos as the source of callus (pg 417, column 2, paragraph 1).

Green (1982, Proc. Fifth Internat. Cong. Plant Tiss. and Cell Cult., pages 107-108) teaches that embryogenic maize callus has the advantages of easy visual observation and extensive duration of regenerability in culture (pg 107, paragraphs 1, 2 and 4).

Vasil et al (1987, Theor. Appl. Genet. 73:793-798) reiterate maize's recalcitrance to regeneration in their teaching that protoplasts of an embryogenic maize culture rarely yielded callus themselves, and that while resultant callus yielded somatic embryos, they were unable to produce whole plants (pg 793, abstract and penultimate paragraph of column 1).

Rhodes et al (1988, BioTechnol. 6:56-60) teach that even when whole maize plants were produced from protoplasts that had formed embryogenic callus, the plants were sterile (paragraph spanning pg 58-59).

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In addition, obtaining whole transformed maize plants requires embryogenic cells that are competent for both transformation and plant regeneration, in contrast to shoot meristems, as taught by Potrykus (1990, BioTechnol. 8:535-542; see paragraph spanning pg 540-541).

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate methods for producing a fertile transgenic maize plant from a multitude of non-exemplified cell and tissue types.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 10-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 10 is indefinite because in step (ii) cells comprising the preselected DNA sequence are identified, while in step (iii) the DNA that comprises the preselected DNA sequence is expressed. The DNA that comprises the preselected DNA sequence cannot be expressed unless cells comprising it are identified in step (ii).

It is unclear in claims 16-18 if the sequence encoding the HD73, HD1 or DH1 endotoxins, respectively, is present in addition to the sequence encoding an endotoxin recited in claim 10 or if Applicant intends that the endotoxin is the Hd-73, HD-1 or DH-1 endotoxin. If the latter, it is suggested that the claims be amended to replace "preselected ... encoding" with --endotoxin is--.

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It is unclear in claim 19 where the promoter is located relative to the DNA sequence encoding the endotoxin and the selectable marker or reporter gene.

Claim 20 lacks antecedent basis for the limitation "said selectable marker gene" in line 3 as claim 10 does not recite the phrase and claim 11 does not require that the preselected DNA sequence have the selectable marker gene rather than the reporter gene.

Claim 20 is indefinite in its recitation of "a promoter operably linked to said selectable marker gene". Genes consist of regulatory elements, like promoters, as well as coding sequences. It is unclear where the promoter recited in claim 20 is located relative to the promoter that is part of the selectable marker gene.

Claims 20 and 25 lack antecedent basis for the limitation "the DNA encoding said endotoxin" in lines 2 and 1, respectively.

It is unclear in claim 21 if Applicant intended that the preselected DNA sequence comprises a selectable marker gene.

Claims 23-24 lack antecedent basis for the limitation "the compound".

The term "increased" in claim 25 is a relative term that renders the claim indefinite. The term "increased" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What is the number of maize-preferred codons increased relative to?

Claim 26 lacks antecedent basis for the limitation "the DNA encoding the *Bacillus thuringiensis* endotoxin" in lines 1-2.

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Claim 27 lacks antecedent basis for the limitation “the truncated *Bacillus thuringiensis* endotoxin” in line 1.

Claims 28-29 lack antecedent basis for the limitation “the preselected DNA” in line 1

Claim 29 lacks antecedent basis for the limitation “the DNA encoding the endotoxin” in lines 2-3.

It is unclear in claim 30 where the manopine synthase, nopaline synthase or octopine synthase promoter is located relative to the DNA sequence encoding the endotoxin and relative to the promoter recited in claim 19.

It is unclear in claim 32 if any members of the population of plants comprise the preselected DNA sequence. It is also unclear if the parent plants are parent plants of the members of the population or if the members of the population are the parent plants.

### ***Double Patenting***

12. Claim 32 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,484,956 in view of Adang et al (US 5,380,831, filed September, 1988). Although the conflicting claims are not identical, they are not patentably distinct from each other because plants comprising a sequence encoding a Bt endotoxin, as claimed in the issued patent, would be a population of plants comprising a sequence encoding a Bt endotoxin, as claimed in the instant application.

13. Claims 11-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 50-51 and 57-58 of copending Application No. 07/508,045. Although the conflicting claims are not identical, they



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are not patentably distinct from each other because a process for producing fertile transgenic maize plants by bombardment with a microprojectile coated with DNA comprising a sequence encoding a Bt endotoxin and a selectable marker gene, as claimed in the copending application is obvious over a process for producing fertile transgenic maize plants by bombardment with a microprojectile coated with DNA comprising a sequence encoding a Bt endotoxin and a selectable marker gene, as claimed in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm. Sometime in January 2004, the examiner's phone number will change to 571-272-0801.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.

December 18, 2003

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180 1638

